



*Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “The court must accept all well-pleaded facts as true, and view them in the light most favorable to the plaintiff.” *Inclusive Communities Project, Inc. v. Lincoln Prop. Co.*, 920 F.3d 890, 899 (5th Cir. 2019) (“*ICP*”) (cleaned up; internal quotations omitted). Further, “[a]ll questions of fact and any ambiguities in the controlling substantive law must be resolved in the plaintiff’s favor.” *Id.* (quoting *Lewis v. Fresne*, 252 F.3d 352, 357 (5th Cir. 2001)). “On the other hand, courts are not bound to accept as true a legal conclusion couched as a factual allegation.” *Id.* (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Further, the court’s analysis is “limited to (1) the facts set forth in the complaint, (2) documents attached to the complaint, and (3) matters of which judicial notice may be taken under Federal Rule of Evidence 201.” *Id.* “When a defendant attaches documents to its motion that are referenced in the complaint and are central to the plaintiff’s claims, however, the court can also properly consider those documents.” *Id.*

## **II. The Motion to Dismiss Should Be Denied Because Plaintiffs Have Alleged a Plausible Claim.**

Plaintiffs allege in their Complaint that the deeming provision of the Tobacco Control Act, 21 U.S.C. § 387a(b), impermissibly delegates legislative power to the Executive branch, and is therefore unconstitutional and unenforceable. Complaint ¶¶52-68. In particular, Plaintiffs allege that the deeming provision imposes no limitations on the Secretary’s discretion with respect to which “tobacco products” should be subjected to the TCA. Plaintiffs quote the FDA’s own representations made to another federal court, and in the Deeming Rule itself, admitting that the deeming provision imposes no meaningful limitations on the Secretary’s discretion. Compl. ¶¶59-60.

If these allegations are true—that is, that the deeming provision imposes either no limits, or some limits that are still constitutionally insufficient—then Plaintiffs have clearly stated a plausible claim to relief that survives a motion to dismiss. Indeed, Plaintiffs rely in large part on binding Supreme Court authority that is materially analogous, *see Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), except that the Complaint sufficiently alleges that the deeming provision here is even *more* unbounded than the authority struck down in that case. In analyzing a Rule 12(b)(6) motion to dismiss, the Court is required to accept Plaintiffs’ factual allegations as true, and “*any ambiguities in the substantive law* must be resolved in the [P]laintiffs’ favor” as well. *ICP*, 920 F.3d at 899 (*italics added*). Consequently, and especially given *Panama Refining*, Plaintiffs have easily stated a plausible claim for relief, and the motion must be denied.<sup>1</sup> In fact, Plaintiffs have demonstrated not merely a plausible claim but likelihood of success on the merits in the context of their injunction motion. Plaintiffs incorporate here their argument as to likelihood of success on the merits as contained in their motion for preliminary injunction (ECF 17 at 33-43 (Argument section II) and reply in support thereof (ECF 29 at 3-13 (Argument section I)).

The Defendants’ motion to dismiss should, therefore, be denied.

### **III. The Motion to Dismiss Should Be Denied Because Plaintiffs Are Entitled to Reasonable and Necessary Discovery.**

Even if the sufficiency of Plaintiffs’ allegations were in doubt, however, the Court should deny the motion to dismiss because Plaintiffs are entitled to reasonable discovery. Plaintiffs require at least some discovery in this case, for two independent reasons.

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<sup>1</sup> This is distinguishable from situations in which a complaint is properly dismissed where a plaintiff’s claim, however factually elaborate, fails simply because there is no valid cause of action under the relevant substantive law. *See, e.g., Collins*, 224 F.3d 496 (dismissing suit because plaintiff shareholders are not within the class of beneficiaries who have a right to sue in contract under New York law).

**a. Refutation of Defendants' voluminous references to factual material outside the pleadings.**

First, discovery is necessary to refute the background picture the Defendants attempt to paint with their voluminous (but superficial) references to factual material outside Plaintiffs' Complaint.

To be clear, *Plaintiffs object, with respect to the resolution of the instant motion to dismiss, to the consideration of any evidence or factual material referenced by Defendants in their combined memorandum.* It is well-established that the only facts that may be considered in resolving a motion to dismiss are those stated in the complaint, in documents attached to the complaint, or matter the proper subject of judicial notice and which is, in fact, judicially noticed. *ICP*, 920 F.3d at 899; *Scanlan v. Texas A&M University*, 343 F.3d 533, 536-37 (5th Cir. 2003). Defendants filed a combined memorandum in which they argue both in opposition to Plaintiffs' injunction motion and in favor of their own motion to dismiss. ECF 25. The memorandum is replete with references to factual material, including scientific studies, that are woven into Defendants' argument on the merits of the nondelegation claim but are wholly outside of Plaintiffs' complaint.<sup>2</sup> Defendants purport to use these materials both to paint a background picture for the Court (thereby coloring the Court's frame of reference or view of ENDS industry in general) and to burnish certain specific points with respect to the application of the nondelegation principle to the challenged statute/regulations. Plaintiffs summarize *some* of the factual matter Defendants have impermissibly sought to rely upon, and provide a statement of the information Plaintiffs intend to secure during an appropriate discovery phase in response.

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<sup>2</sup> Even if a plaintiff attaches or incorporates parts of a certain document in his complaint, that does not open the door for a defendant to rely on other parts of even that same document to support a motion to dismiss over plaintiff's objection. *Scanlan*, 343 F.3d at 536-39.

Some of the factual material cited by Defendants is potentially relevant to the nondelegation claim in a broad sense:

- Both parties cite the statement in *Whitman v. American Trucking Associations*, 531 U.S. 457, 475 (2001), that “the degree of agency discretion that is acceptable varies according to the scope of the power” delegated. *See Plfs’ Mem.* at 34; *Defs’ Mem.* at 34. Defendants quote this statement and imply that the Deeming Rule is similar in scope of economic impact to the example regarding “country elevators” (*i.e.*, not much economic impact at all), while Plaintiffs cited this statement as part of their argument that the Deeming Rule has a broad economic impact and therefore requires more substantial guidance from Congress and judicial scrutiny. *Plfs’ Mem.* at 34. This is a fact issue calling for economic data. Plaintiffs are entitled to the opportunity to secure admissible evidence reflecting the size of the ENDS industry and other newly-deemed industries (cigars, etc.), the jobs at stake, etc., before the Court can determine how this factor affects the challenge here.
- Defendants begin their memorandum with a recitation of the dangers that purportedly animated Congress in passing the TCA in 2009, suggesting that subjecting ENDS to the TCA is obviously consistent with Congress’ intent and purpose. *Defs’ Mem.* at 3-5. This section relies on parts of the legislative record that are discussing studies undertaken years, and even decades, before ENDS were on the market in the US, and which focused primarily on the dangers of *combustible* tobacco products. As with the rest of the evidentiary materials referenced, these are not materials that Plaintiffs rely upon or incorporate in their Complaint. Plaintiffs must have the opportunity to adduce admissible evidence reflecting the fact that combustible tobacco products are far more dangerous than vapor products, thus undermining Defendants’ attempt to simply extrapolate such concerns as if they applied with the same force here.

If Defendants wanted to provide the Court with the opportunity to dismiss Plaintiffs’ case entirely as a matter of law, they could have filed a separate memorandum in favor of their motion to dismiss, limited to the discussion of the nondelegation jurisprudence and relevant legal facts. Instead, they filed the combined memorandum relying on voluminous extraneous facts. By doing so, they have forfeited their opportunity to seek final dismissal on the merits *without any discovery*.

Plaintiffs note that they do not concede that any of Defendants’ arguments or evidence actually undermine the constitutional challenge—the fact is that the deeming provision is unconstitutional on its face for the same reasons that animated *Panama Refining*. Nonetheless,

Plaintiffs are not required to concede their opportunity to secure admissible evidence that may be necessary to refute or contextualize any evidence that the Defendants may want to adduce in this case, either now or in a later motion or proceeding. In other words, while Plaintiffs will argue that they should win as a matter of law without any further discovery, they do not have to assume that this (or a higher) Court will entirely agree, and concede their right to discovery. Plaintiffs have a right to use necessary discovery tools to secure evidence that is relevant to their claims.

The fact that Plaintiffs have submitted evidence in relation to their preliminary injunction motion (which is not at issue with respect to the instant motion to dismiss) does not suffice for actual discovery to seek admissible evidence for the merits. Plaintiffs were limited to proffering whatever information was available at hand and without the aid of discovery tools.

**b. Discovery relevant to Plaintiffs' claims irrespective of Defendants' motion to dismiss.**

Even independent of Defendants' motion to dismiss, Plaintiffs are entitled to a period of appropriate discovery related to the merits of their claims.

For one, Plaintiffs have reason to believe that discovery in this particular case will yield evidence that will undermine a commonly-recited practical justification for broad delegations by illustrating that delegating too broadly can actually *undermine* that same justification.

The Court has long recognized that Congress may “obtain[] the assistance of its coordinate branches” within constitutional bounds, *Mistretta v. United States*, 488 U.S. 361, 372 (1989), and “the extent and character of that assistance must be fixed according to common sense and the inherent necessities of the government co-ordination.” *Id.* (quoting *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 406 (1928)). It is in this vein that some delegation cases refer to the necessity of delegating fact-finding functions or other discretion to “experts” in the Executive branch, to deal with the minutiae that Congress purportedly cannot

attend to. While this may be true within constitutional limits, Plaintiffs contend that this case aptly illustrates that delegating too much authority—the authority to make the policy that Congress is required to make—not only short-circuits the legislative process so carefully enshrined in the Constitution and vested in the two Houses of Congress, *but also undermines the proper functioning of the experts and agencies of the Executive.*

When operating within its constitutional limitations, as the science- and evidence-based agency that it claims to be, the FDA (and CDC, etc.) meets a critical public function. But vesting it with unilateral authority (as part of the Executive branch) to make legislative decisions skews the FDA's motivations and incentives, which can have the effect of subjugating the science to the policy agenda. This has been illustrated here in the way the FDA and CDC have obfuscated the results of the National Youth Tobacco Survey. The FDA has relied on the results of the survey to justify its indiscriminate regulation of ENDS, citing an undifferentiated uptick in youth vaping. Plaintiffs contend, however, that the results of that survey, and other evidence, reflect clearly that the uptick in youth vaping is attributable *almost entirely* to a distinctive subset of vaping products (namely, Juul and other pod-based, closed systems), and not the open-system devices that the USVA's members sell. FDA knows this, but has deliberately obfuscated and generalized the survey results in all its public comments because it wants to piggyback its policy agenda—regulating vaping in general—on the cited uptick in youth vaping. These are the kinds of distinctions that can be made—and that interested parties have more opportunity to influence—in the legislative process in Congress. Similarly, Plaintiffs intend to secure admissible evidence reflecting that the FDA and CDC have deliberately obfuscated and sensationalized the recent lung illnesses—consistently referring to them as “vaping” illnesses—when it should have been obvious (and likely *was* obvious) that these illnesses arose from black-

market THC-based products, not nicotine e-liquids such as are at issue in this case (just as it was obvious to the USVA's members). Plaintiffs intend to seek admissible evidence reflecting that the policy motivations accompanying the broad policy discretion delegated here have tainted and undermined the ability of the FDA and CDC to perform the legitimate function they should be performing.

In short, Plaintiffs should be entitled to an appropriate discovery phase in order to secure admissible evidence that may tend to make any fact relevant to their claims more probable than it would be without the evidence. *See* Fed. R. Evid. 401.

**PRAYER**

Plaintiffs respectfully request the Court deny Defendants' motion to dismiss. Plaintiffs further request any additional relief to which they may be justly entitled.

Respectfully submitted,

FORMAN WATKINS & KRUTZ LLP

/s/Spencer M. Ritchie

Spencer M. Ritchie

Mississippi Bar No. 103636

210 E. Capitol Street, Suite 2200 (39201)

P.O. Box 22608

Jackson, MS 39225-2608

Tel.: (601) 960-8600

Fax: (601) 960-8613

spencer.ritchie@formanwatkins.com

NAJVAR LAW FIRM, PLLC

Jerad Wayne Najvar\*

Texas Bar No. 24068079

jerad@najvarlaw.com

Austin M.B. Whatley\*

Texas Bar No. 24104681

austin@najvarlaw.com

2180 North Loop W., Suite 255

Houston, TX 77018



Tel.: (281) 404-4696

Fax: (281) 582-4138

\*Motion for admission *pro hac vice* forthcoming.

*Counsel for Plaintiffs*

**Certificate of Service**

I do hereby certify that I have electronically served the foregoing Reply using the Court's ECF system, which sent notification to all known counsel of record.

THIS, the 20th day of November, 2019.

/s/ Spencer M. Ritchie  
Spencer M. Ritchie